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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Hagit AMITAL, et al

Art Unit: 1646

App. No.: 09/807,610

Conf. No.2065

Examiner: Ruixiang Li

Filed: April 16, 2001

Washington, D.C.

For: EXPRESSION AND SECRETION OF ICIL-1 RECEPTOR ANTAGONIST TYPE II

Atty.'s Docket: AMITAL=1

Date: September 6, 2002

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is a [] Amendment [XX] Response to Restriction Requirement
in the above-identified application.

- [] Small Entity Status: Applicant(s) claim small entity status. See 37 C.F.R. §1.27.
[] No additional fee is required.
[] The fee has been calculated as shown below:

	(Col. 1)		(Col. 2)	(Col. 3)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA EQUALS
TOTAL	*	MINUS	** 20	0
INDEP.	*	MINUS	*** 3	0
FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				

ADDITIONAL FEE TOTAL

SMALL ENTITY

RATE	ADDITIONAL FEE
x 9	\$
x 42	\$
+ 140	\$
ADDITIONAL FEE TOTAL	

OR

OTHER THAN SMALL ENTITY

RATE	ADDITIONAL FEE
x 18	\$
x 84	\$
+ 280	\$
TOTAL	

OR

- * If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.
** If the "Highest Number Previously Paid for" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid for" IN THIS SPACE is less than 3, write "3" in this space.

The "Highest Number Previously Paid For" (total or independent) is the highest number found from the equivalent box in Col. 1 of a prior amendment of the number of claims originally filed.

[XX] Conditional Petition for Extension of Time

If any extension of time for a response is required, applicant requests that this be considered a petition therefor.

- [] It is hereby petitioned for an extension of time in accordance with 37 CFR 1.136(a). The appropriate fee required by 37 CFR 1.17 is calculated as shown below:

Small Entity

Response Filed Within

- [] First - \$ 55.00
[] Second - \$ 200.00
[] Third - \$ 460.00
[] Fourth - \$ 720.00

Month After Time Period Set

Other Than Small Entity

Response Filed Within

- [] First - \$ 110.00
[] Second - \$ 400.00
[] Third - \$ 920.00
[] Fourth - \$ 1440.00

Month After Time Period Set

- [] Less fees (\$) already paid for ___ month(s) extension of time on _____.

- [] Please charge my Deposit Account No. 02-4035 in the amount of \$_____.

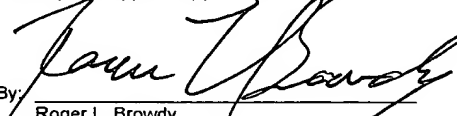
- [] Credit Card Payment Form, PTO-2038, is attached, authorizing payment in the amount of \$_____.

- [] A check in the amount of \$_____ is attached (check no.).

- [XX] The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035. This authorization and request is not limited to payment of all fees associated with this communication, including any Extension of Time fee, not covered by check or specific authorization, but is also intended to include all fees for the presentation of extra claims under 37 CFR §1.16 and all patent processing fees under 37 CFR §1.17 throughout the prosecution of the case. This blanket authorization does not include patent issue fees under 37 CFR §1.18.

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Atty. Docket: AMITAI=1

In re Application of:) Conf. No.: 2065
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Hagit AMITAI, et al) Art Unit: 1646
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Appln. No.: 09/807,610) Examiner: Ruixiang Li
)
Filed: April 16, 2001) Washington, D.C.
)
For: EXPRESSION AND SECRETION) September 6, 2002
OF ICIL-1 RECEPTOR)
ANTAGONIST TYPE II)

RESPONSE

Honorable Commissioner for Patents
Washington, D.C. 20231

Sir:

The present communication is responsive to the Official action of August 6, 2002. Claims 1-15 presently appear in this case. All of the claims have been subject to a restriction requirement. Reconsideration and withdrawal of the restriction requirement and examination on the merits and allowance of all the claims now present in the case is respectfully urged.

The examiner has required restriction among the following three groups:

Group I, including claims 1-12, drawn to an expression vector, a host cell, a recombinant icIL-1ra-II, a method for producing icIL-1ra-II, and a pharmaceutical composition comprising same;

Group II, including claim 13, drawn to a method for reducing the amount of IL-1 in a patient by administering a

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pharmaceutical composition comprising the glycosylated icIL-1ra-II;
and

Group III, including claims 14 and 15, drawn to a method for reducing the amount of IL-1 at a desired site in a human patient by introducing an expression vector into an appropriate endogenous human cell at the desired site to produce transformed cells which will express icIL-1ra-II.

The examiner states that the Groups do not relate to a single general inventive concept because the technical feature linking Groups I to III appears to be the intracellular IL-1 receptor antagonist and the nucleic acid encoding same while the prior art teaches cloning and characterization of an intracellular form of the human interleukin-1 receptor antagonist, citing Haskill and Muzio. This restriction requirement is respectfully traversed.

Haskill and Muzio relate only to the intracellular form of the IL-1 receptor antagonist. However, the single general inventive concept of the present invention is the provision of an expression vector which includes a signal peptide joined to the DNA segment of the prior art. All of the claims include this expression vector and rely on this expression vector or the novel glycosylated protein expressed therefrom, as a special technical feature. It is not disclosed or made obvious by either of the references cited by the examiner, both of which were only cited as being in Category A by the international examiner. The DNA encoding the endogenous intracellular protein has no signal peptide and was found to be expressed constitutively intracellularly only. Reference is made to

the background of the invention and the detailed description of the present invention, particularly at pages 4 and 5.

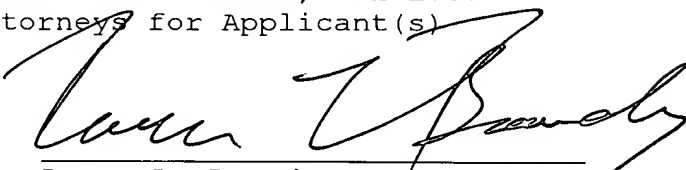
In order to be responsive, applicant hereby elects the invention of Group I with traverse. At least the first method of use as set forth in Group II, should be examined with the claims of Group I. Furthermore, it would not create a serious burden for the examiner to also search and examine claims 14 and 15 on the merits so that all of the claims may be examined and issued from a single application.

Accordingly, reconsideration and withdrawal of the restriction requirement and prompt examination on the merits and allowance of all the claims now present in the case is earnestly solicited.

Respectfully submitted,

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